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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/580,549	SCHNABELRAUCH ET AL.	
	Examiner	Art Unit	
	Jeffrey T. Palenik	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 September 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-7,9-29,31 and 40-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-7,9-29,31 and 40-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

STATUS OF THE APPLICATION

Receipt is acknowledged of Applicants' Amendments and Remarks, filed 23 September 2010, in the matter of Application N° 10/580,549. The Examiner further acknowledges the following:

Claims 3, 30 and 32-39 have been canceled.

Claims 1, 2, 5, 10-14, 19, 24, 26, 27-29 and 31 have been amended. Of particular note is that claim 2 has been amended with the limitations of canceled claim 3. Claims 27 and 28 have been amended to remove the more broadly recited limitations. Said limitations have been imported into claim 1. Claims 4-7 are amended editorially as are claims 9-14. Claims 7, 11, 19 and 24 are amended to overcome the indefiniteness rejections as discussed below. Support is provided for the amendments.

Claims 40-43 have been added. Support for the added limitations is provided.

No new matter has been added.

Thus, claims 1, 2, 4-7, 9-29, 31 and 40-43 now represent all claims currently under consideration.

INFORMATION DISCLOSURE STATEMENT

No new Information Disclosure Statements (IDS) have been filed for consideration.

WITHDRAWN OBJECTIONS/REJECTIONS

Objections to the Claims

Applicants' amendments to claims 2 and 26 are sufficient in overcoming the objection on the grounds that the claims do not further limit their respective parent claims. The objection to claim 30 is rendered moot since the claim has been canceled.

Rejections under 35 USC 112

Applicants' amendment to the claim 13 removing the "prophylaxis" limitation is sufficient to overcome the enablement rejection raised under the first paragraph of 35 USC 112. As such, the rejection stands **withdrawn**.

Applicants' amendments to claims 2, 5, 10-11, 14, 19, 24 and 26-31 removing the "particularly" and/or "especially" limitations are sufficient in overcoming the indefiniteness rejections raised under the second paragraph of 35 USC 112. As such, the rejections stand **withdrawn**. In the case of claim 30, the rejection is moot since the claim has been canceled.

Rejection under 35 USC 102

Applicants' amendment to the base claim inserting calcium phosphate and its property limitations previously recited by claims 27 and 28, is sufficient in overcoming the anticipation rejection raised under 35 USC 102(b) over the machine translation provided for Schnabelrauch et al. (DE 199 39 403). As this particular form of calcium phosphate is not expressly taught by the reference, the rejection stands **withdrawn**.

MAINTAINED OBJECTIONS/REJECTIONS

The following objections and/or rejections are maintained from the previous Office Correspondence dated 23 March 2010 since the art which was previously cited continues to read on the amended/newly cited limitations.

SPECIFICATION

ARRANGEMENT OF THE SPECIFICATION

As provided in **37 CFR 1.77(b)**, the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.
(b) CROSS-REFERENCE TO RELATED APPLICATIONS.
(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
(d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
(e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.

(f) BACKGROUND OF THE INVENTION.
(1) Field of the Invention.
(2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.

(g) BRIEF SUMMARY OF THE INVENTION.
(h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
(i) DETAILED DESCRIPTION OF THE INVENTION.
(j) CLAIM OR CLAIMS (commencing on a separate sheet).
(k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
(l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

RESPONSE TO REMARKS

Applicants allege that the specification is in an acceptable format and that no amendments are needed; an assertion with which the Examiner partially and respectfully disagrees.

Concerning the Abstract of the Invention, the Examiner has reconsidered the objection and withdraws it. However, concerning the arrangement of the specification, the Examiner maintains the objection on the grounds that Applicants discuss the state of the prior art within the Description of the Invention. Description of the Related Art is not a description of the instant invention. Rather it is a discussion of the Background of the invention (e.g., what is known about the closest prior art and/or problems to be overcome, etc.).

For this reason, Applicants' arguments are found unpersuasive and the objection is **maintained**.

CLAIM REJECTIONS - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 14 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter that is not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Claim 14, as discussed above, recites such general pharmaceutically active ingredients as

"proteinogenic growth factors". While the Examiner acknowledges that the term "proteinogenic growth factors" is mentioned in the instant specification, the term is not defined by the instant specification in a clear and concise manner. As such, the disclosure of the instant specification is not sufficient to support the generic concept of "proteinogenic growth factors" and requires further clarification. A brief search of the prior art concerning the instantly claimed term resulted in the instant application only. At present, it appears that no clear definition may be construed from the prior art, and the Examiner is unable to interpret the term for the purposes of examination on the merits.

RESPONSE TO ARGUMENTS

Applicants' remarks with regard to the written description rejection of claim 14 under 35 USC 112, first paragraph, have been fully considered but they are not persuasive.

It is not expressly clear to the Examiner, but it appears as though Applicants traverse this particular rejection at the third paragraph of page 11 of the Remarks. If this is the case, then it appears that Applicants traverse the rejection on the grounds that the Draenert reference provides "sufficient general knowledge" for the implementation of pharmacologically active agents into an implementation material (e.g., bone cement).

In response, the Examiner respectfully maintains the rejection since Applicants appear to simply assert that what is known in the prior art concerning "proteinogenic growth factors" is "generally" and adequately described by the teachings of Draenert et al., presently made of record. After reconsidering the Draenert reference the Examiner respectfully further maintains that there is no discussion whatsoever within the reference which would convey to the ordinarily

skilled artisan a description of what "proteinogenic growth factors" might embody.

For this reason, Applicants' arguments are found unpersuasive. Said rejection is therefore **maintained**.

CLAIM REJECTIONS - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 17 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schnabelrauch et al. with respect to the claims as set forth above.

The limitations and teachings of claims 1, 2, 4-7, 9-11, 15, 18-19, 21-26, 28, 29 and 31 are discussed above and are *reproduced here for Applicants' convenience*:

The instant invention of claim 1 is drawn to a method for producing a self-hardening bioabsorbable composite, wherein a polymerization initiator ("initiator") is mixed with an interconnectingly porous bioabsorbable inorganic bone regeneration material (herein, "bone regeneration material" or "BRM") and a polymerization activator (herein "activator") is also mixed with a bone regeneration material. The bone regeneration material in the case of the separate mixings may either be the same or different. The initiator mix and activator mix are then combined with one another with a third component which is a multi-functional monomer(s), which is in either liquid or paste form. An additional limitation to the base claim is that at least one of the constituents mixed therein is a water-soluble pore-forming substance which is added to the monomer(s). Claims 3 and 4 recite that one or more modifying constituents are added to the mixture (e.g. thickeners or viscosity modifier). Claims 5 and 6 further limit claim 4 in terms of the composition of the viscosity-modifying constituent (e.g. dianhydro-D-glucitol-bis(poly-D,L-lactide)). Claim 7 recites that at least one of the constituents added in the process of claim 1 is water soluble. Claim 7 alternatively recites that at least one of the constituents employed in the method of claim 1 is one which reacts with water to form a water-soluble resultant product and one which brings about a change in pH. Claim 9 recites that such a compound is sodium hydrogen carbonate (e.g. sodium bicarbonate). Claims 10 and 11 recite that the composition has added to it an agent which imparts adhesive properties between the finished composite and

hard tissues (e.g. methacrylic acid-2-hydroxyethyl ester). Claim 15 recites that the amount of bone regeneration material mixed with the initiator (BRM_i), and the amount mixed with the activator (BRM_{ii}), is present at a ratio range of 1:10 to 10:1 (i.e. (BRM_i): (BRM_{ii}) = 1:10 to 10:1). Claim 18 recites that the polymerization initiator is a solution which is admixed with the bone regeneration material in an amount ranging from 0.1-20 wt%. Claim 19 recites that said initiator comprises an organic peroxide (e.g. dibenzoyl peroxide). Claim 21 recites that the polymerization activator is a solution which is admixed with the bone regeneration material in an amount ranging from 0.1-20 wt%. Claim 22 recites that said activator comprises such compounds as N,N-bis(2-hydroxyethyl)-p-toluidine. Claim 23 recites that both the activator and initiator compounds are used in the form of solutions and that they are mixed with the bone regeneration material. Claim 24 recites limitations to the bone regeneration material (e.g. calcium phosphate). Claim 25, as discussed above, recites that the bone regeneration materials mixed with the initiator and the activator are the same. Claim 26 recites that said materials are different. Claim 28 is broadly and reasonably interpreted as reciting that the method of claim 1 uses an interconnectingly porous bone regeneration material, thereby reciting the same subject matter as the base claim. Claim 29 recites that the bone regeneration material is crystalline, partially crystalline, glassy or amorphous. This is broadly and reasonably interpreted by the Examiner as reciting that said bone regeneration material may be in a form on any level of ordered structure. Claim 30, as discussed above, is broadly and reasonably interpreted by the Examiner as reciting the same subject matter as claims 1 and 2. Claim 31 recites that the monomer or monomer mixture of claim 1 comprises terminal methacrylate groups.

Schnabelrauch et al. teach the preparation of the instant invention in Examples 4-6 of the DE '403 patent.

Initiator	25 Parts
	94.67 wt% calcium carbonate
	5.33 wt% dibenzoyl peroxide
Activator	25 Parts
	96.0 wt% calcium carbonate
	4.0 wt% bis-N,N-(2-hydroxyethyl)-p-toluidine
Polymerizing/Thickening Agent	50 Parts
	56 wt% dianhydro-D-glucitol-bis-[(oligo-L-lactyl) methacrylate]
	12 wt% methyl methacrylate
	12 wt% methacrylic acid-2-hydroxyethyl ester
	20 wt% dianhydro-D-glucitol-bis-(oligo-D,L lactide)

The Examples teach the separate formulation of the initiator/bone regeneration material and the activator/bone regeneration material mixtures as well as their ultimate mixture with the methacrylate-terminated monomer mixture (claim 31) and viscosity enhancing agent of claim 6. Per the Examples, the bone regeneration material mixed with both the initiator and activator are the same. The incorporation of water-soluble methacrylic acid-2-hydroxyethyl ester expressly teaches the limitations of claims 7, 10 and 11. Example 1 expressly teaches the alternative limitations of claims 7 and 9 wherein a sodium bicarbonate solution is employed in the formation of the dianhydro-D-glucitol-bis-[(oligo-L-lactyl) methacrylate] component of the

composite. The amounts of bone regeneration material used in each of the initiator and activator mixtures are present in about a 1:1 ratio (e.g. 94.67:96). Dibenzoyl peroxide in the amount of 5.33 wt% reads on claims 18 and 19. The use of 4.0 wt% bis-N,N-(2-hydroxyethyl)-p-toluidine reads on claims 21 and 22. Preparation of "Component B" (e.g. the initiator), per the DE '403 patent, is taught wherein the filler (e.g. bone regeneration material) is treated with a solution of the polymerization initiator with subsequent removal of the solvent (pg. 3 of the machine translation, lines 14-19). The preparation of the instant activator mixture is similarly taught in terms of "Component C" (pg. 3 of the machine translation, lines 22-27). Concerning the bone regeneration material limitations of claim 24, though the Examples are specifically and preferably drawn to formulations which employ calcium carbonate, the DE '403 also teaches the preferred use of such materials as calcium carbonate and hydroxyapatite (pg. 3 of the machine translation, lines 10-13). The same passage is further interpreted by the Examiner as teaching the limitations of claim 26 (objected to above), wherein mixtures of the preferred bone regenerating materials are used for forming Components "B" and "C". Thus the reference teaches each and every one of the instantly claimed limitations.

Claims 17 and 20 respectively recite, with regard to the preparation of the initiator mixture and the activator mixture that once said mixtures are formed, they are dried and then mixed with the liquid component of step (iii). The machine-translated text of the DE '403 patent does not expressly teach that each of the components are dried prior to mixture with one another. However, the methods for forming both Components "B" and "C" (e.g. initiator and activator mixtures, respectively) do teach that the filler (e.g. bone regeneration material) in each

component is mixed with an initiator solution (e.g. for "B") and an activator solution (e.g. for "C") and then subjected to the removal of the excess solvents. When considered in terms of Examples 4-6 wherein the filler material consists of 94.67% or greater of the component, it stands to reason that the removal of the excess liquid from the preparations would result in a relatively dry product.

It thus follows that the ordinarily skilled artisan would have had a reasonably high expectation of arriving at and achieving the instantly claimed method given the teachings that a small amount of initiator and/or activator solutions are initially admixed with the filler compound and then the excess liquid solvent removed. Such a teaching would have motivated the skilled artisan towards producing a dried product as a result of employing said method. Thus, in light of the forgoing interpretation and guidance of the prior art, it would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to have prepared a self-hardening bioabsorbable composite material such that a dried activator composition and dried initiator composition are admixed per the instant claims.

Claims 12-14, 16, 24, 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schnabelrauch et al. with respect to claim 1 as set forth above, further in combination with Draenert (USPN 4,373,217).

The limitations of claim 1 are discussed above. Claim 12 recites that at least one of the constituents employed in the method of claim 1 is a colorant or contrasting agent. Claims 13 and 14 recite that at least one of the constituents employed in the method of claim 1 is a pharmaceutically active ingredient such as an antibiotic or anti-inflammatory agent. Claim 16

recites that the bone regeneration material used in the method is in the form of a powder or granules. The limitations of claim 24 are discussed above and are further noted as reciting more specific bone regeneration materials such as tricalcium phosphate. Claim 27 recites that the bone regeneration material employed in the method, such as calcium phosphate, are particles which have the following characteristics: pore diameters which range in size from 0.1-500 microns, particle sizes which range in size from 1-500 microns and a "BET" surface area of at least $0.1m^2/g$. The limitations of claim 28 are discussed above, and are noted as further reciting more specific limitations for the bone regeneration material wherein it is calcium phosphate particles having a pore volume ranging from 0.4-3.3 mL/g (e.g. 400-3,300 μL/g).

The teachings to Schnabelrauch are discussed above. **Of particular note is that calcium phosphate is expressly taught as a preferred filler or bone regeneration component. However, none of the property limitations recited in claims 16, 27 or 28 are expressly taught.** Similarly, none of calcium phosphate species recited in claim 24 are taught. Also Schnabelrauch does not teach the incorporation of colorants or active ingredients into the composite prepared. However, the forgoing deficiencies are remedied by the teachings of Draenert et al.

The invention practiced by Draenert is drawn to tricalcium phosphate-based implantation materials (Abstract) which may be ultimately utilized as bone replacement or bone bonding/prosthesis material (col. 1, lines 6-10). Concerning the limitations of claim 24, Draenert teaches the use of more specific forms of porous calcium phosphate (e.g. tricalcium phosphate) (e.g. Examples 1 and 3a). Concerning the limitations of claim 12, Example 1 again expressly teaches the inclusion of chlorophyll in the bone cement mixture. Such a teaching is necessarily

interpreted as reading on the limitations of the claim given that an inherent property of chlorophyll is that it is a pigment which is found in most plants, algae and cyanobacteria, as is well known in the art (e.g. http://en.wikipedia.org/wiki/Chlorophyll). The ordinarily skilled artisan, in light of MPEP 2112.01, would highly expect the same pigmentation property to be conveyed in the teachings of Draenert, given that chemical compounds and their properties are not mutually exclusive. Concerning the limitations of claims 13 and 14, Draenert teaches the inclusion of antibiotic compounds (e.g. "-mycin" compounds) for the express purpose of avoiding or minimizing infections at the site of implantation (col. 6, line 30 to col. 7, line 17). Additional motivation for including such compounds stems from the teaching and suggestion that infections cannot always be prevented even when careful aseptic manipulation of the materials is observed (col. 6, lines 31-34).

Lastly, concerning the particle characteristics of the bone regeneration material, Example 1 teaches the limitations of claim 16 such that the tricalcium phosphate employed is a precipitated (e.g. solid form). As such it is expressly taught, if not suggested, that form used is particular. The average particle size of said tricalcium phosphate is further taught as ranging from 100-200 microns in diameter and having a pore volume of 0.4 mL/g.

Draenert does not expressly teach either the instantly claimed pore diameter or the instantly claimed "BET surface area" range. However, given that the teachings are directed to porous particles whose average diameter ranges from 100-200 microns, it stands to reason that the pores which enable the particles to have a "pore volume" must be less that 100-200 microns in size. It similarly follows that pore diameters of that range overlap and thus render obvious the instantly recited range. With regard to the "BET surface area" limitation recited in claim 27;

until some material difference(s) in the properties of the composition are demonstrated, said limitation is considered by the Examiner to be directed toward particles used in forming the composite of the instantly claimed method. It is further understood that "BET" refers to a theoretical method developed in 1938 by physicists ***B***runauer, ***E***mmett and ***T***eller wherein the physical adsorption of gas molecules on a solid surface served as the basis for an analytical technique for the measuring of the specific surface area of a material [***emphases added***] (http://en.wikipedia.org/wiki/BET_theory). It is respectfully pointed out that the Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether Applicants' method for using tricalcium phosphate particles comprising said property differs from and, if so, to what extent, from that which is taught and suggested by the reference(s). Therefore, with the showing of the reference, the burden of showing a lack of novelty and/or establishing non-obviousness by objective evidence is shifted to the Applicants (MPEP 2113).

Thus, based on the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonably high expectation of successfully arriving at the instantly claimed method. The ordinarily skilled artisan would have been particularly motivated by the combined guidance given the aforementioned advantages for including a pharmaceutically active ingredient and teachings of particle properties. Additional motivation to combine the references is garnered from the comparison of methods for producing the respective bone cements. Both references appear to preferably employ calcium phosphate, dimethyl-p-toluidine, and dibenzoyl peroxide as well as methyl esters of acrylic acid and methacrylic acid for forming the bioabsorbable bone composites.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, alone or in combination, especially in the absence of evidence to the contrary.

RESPONSE TO ARGUMENTS

Applicants' arguments with regard to the rejection of claims 1, 2, 4-7, 9-29 and 31 under 35 USC 103(a) as being unpatentable over the teachings of Schnabelrauch et al. alone and/or in combination with Draenert have been fully considered but they are not persuasive.

Applicants allege that the amendment to claim 1, which as discussed above, incorporates more definitive limitations pertaining to the "interconnectingly porous bioabsorbable inorganic bone regeneration material", is sufficient in overcoming the instant rejections. Specifically, calcium phosphate and its pore diameter, particle size and BET surface properties are now recited in the base claim. Concerning the combination of Schnabelrauch and Draenert, Applicants argue that the amended pore volume limitation (e.g., 0.4 cm^3/g or more) versus that which is taught by Draenert (e.g., less than 0.1 mL/g) presents a teaching away which sufficiently overcomes the second rejection. It is further asserted that the invention of Draenert is not directed to a bioabsorbable composite material as instantly claimed.

With regards to the second and third arguments, the Examiner respectfully disagrees and maintains that while the Draenert reference is admittedly preferably directed to the use of resorbable (e.g., bioabsorbable) tricalcium phosphate having a pore volume of less than 0.1 mL/g, per Applicants' position, that consideration must also be given to the nonpreferred teachings and what they would convey to an artisan of ordinary skill (MPEP §2123). Of

particular note is Draenert's discussion directed to the calcium phosphates which may be formed via precipitation and which have a pore volume ranging from about 0.3-0.5 mL/g. It is acknowledged that the disadvantage discussed pertains to the difficulty in preparing particles possessing this property. However, the irrefutable advantage is that porous calcium phosphate particles having the larger pore volume property are known to be "rapidly resorbed in the body and permit a rapid growth of bone tissue into the thus-formed pores of the cement" (col. 3, line 28 to col. 4, line 12).

Thus, it stands to reason that the combined teachings of Schnabelrauch and Draenert continue to render the instant claims obvious. The deficiency of Schnabelrauch failing to further define the preferred calcium phosphate by its properties is clearly rectified through Draenert, not only in terms of said properties, but also providing motivation for why one of ordinary skill would modify the bone cement particles on the basis of their pore volume.

Consideration and interpretation of the amended calcium phosphate properties of the instant base claim, made in light of the instant disclosure (MPEP §2111), namely the Examples, indicates that the calcium phosphate which is used is the trademarked product CERASORB® (e.g., β-tricalcium phosphate or β-TCP), invented, trademarked and sold by Applicants' Assignee Curasan AG. The Trademark Electronic Search System or "TESS" indicates that a trademark application for the product was filed on 19 September 1999 and published on 11 November 2003. What is even further compelling is that the Curasan website discloses Cerasorb® as being a "fully resorbable, synthetic bone regeneration material filed as the worldwide reference for β-TCP" and "used in more than 800,000 clinical cases and scientifically documented over many years". Further conception and research of the product is clearly indicated as dating back to the

1970's and is stated as having "consistently continued … in the nineties". The product, specifically Cerasorb® M is taught as being an interconnecting, open, multi-porous particle having pore sizes which range from 5-500 microns and having grain (e.g., particle) sizes ranging from 1-8 microns. Lastly, the website advertises that "[a]ll [the] different forms [of Cerasorb®] have been optimized in regard to their surface, porosity and resorption/degradation behavior".

Thus, in light of the evidence provided by TESS as well as Applicants' own website, it can be shown that a calcium phosphate particle meeting Applicants' instantly recited properties was known, available and in use, certainly at the time the Schnabelrauch patent (e.g., DE '403) was published and thus would have been available to a person of ordinary skill in the art at the time of the instant invention.

For these reasons, Applicants' arguments are found unpersuasive. Said rejection is therefore **maintained** and extended to include the limitations of newly added claims 40-43. Newly recited claims 40 and 43 are read upon by the teaching of dianhydro-D-glucitol-bis-(oligo-D,L-lactide) (e.g., oligomeric derivative of lactic and/or glycolic acid). Claim 41 recites the presence of methacrylic acid 2-hydroxyethl ester, a compound which is taught in the formulation of the DE '403 patent (see Table above). Lastly, claim 42 recites the use dibenzoyl peroxide as a polymerization initiator. This component is also taught by the Schnabelrauch patent as discussed above.

All claims under consideration remain rejected; no claims are allowed.

CONCLUSION

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

CORRESPONDENCE

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey T. Palenik whose telephone number is (571) 270-1966. The examiner can normally be reached on 7:30 am - 5:00 pm; M-F (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jeffrey T. Palenik/
Examiner, Art Unit 1615

/Robert A. Wax/
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